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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Rolf Muller

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EXAMINER

ANDERSON, JERRY W

ART UNIT

PAPER NUMBER

1794

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,781	<b>Applicant(s)</b> MULLER ET AL.	
	<b>Examiner</b> JERRY W. ANDERSON	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/19/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Examiner acknowledges the receipt of the Applicant's Amendment, mailed 3/02/2009. Claims 2 and 4 are canceled, claims 1 and 8-10 are amended, and claims 11-15 are new. Specification is amended to address proper use of trademarks.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claim 8, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

5. Regarding claim 10, the phrase "and/or" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

#### ***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. **Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shi.**
8. Shi ('571) discloses:

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- a. resistant, gelatinized, crystallized starch, (lines 6-9 col. 3, lines 34-35, 46-48 col. 4, '571)
  - b. resistant to digestion in the small intestine, and passes into the large intestine, ( line 13-15 col. 1, '571)
  - c. sample 1B 22.7 at 20 min, 48.6 at 120 min, (table 1, '571)
  - d. sample 1D 25 at 20 min, 50.3 at 120 min, (table 1, '571)
  - e. A slowly digestible starch product prepared by enzymatically debranching low amylose starches and allow the resultant linear short chains to crystallize to a highly crystalline form, (lines 20-25, col. 2, '571)
  - f. starch made be used in a variety of edible products . . . cereal, bars . . . dietary supplements, (lines 29-41, col. 5, '571)
9. Regarding Claim 1, the Applicant claims a slow digestible starch product, with a swellable network, crystallites and an initial hydrolysis rate of <300 %/h. *Shi* teaches a resistant, gelatinized, crystallized starch, (lines 6-9 col. 3, lines 34-35, 46-48 col. 4, '571) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, ( line 13-15 col. 1, '571 ) The applicant determines the hydrolysis rate by measuring the amount of undigested starch at intervals of .5, 1, 2, 3, 4, 5, and 6 hours and calculating the digested portion of the starch. This data is shown in Table 1 and plotted in Figures 1-5, applicant's specification) Applicant states that *Shi*'s data is comparable to amylase treated cornstarch, with a  $H_0$  of 200 %hr,  $H_c$  of 200 %/hr and a  $T_c$  of 0.25 hours. (¶ 46, Table 1, Applicant) However, comparison of the data in *Shi*'s Table 1, samples 1B and 1D, the % digested values at 20 min and 120 minutes, which

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are approximately 24 % and 49 %, (table 1, '571) respectively with the applicant's data yields different results. Said data when plotted on the applicants graph in Fig. 3, are similar in performance, if not slightly better than the results of samples WS 72-2 through 4, which have Ho (%/h) of 70-90, Hc (%/h) of 20-22 and Tc (h) of 2.5. When compared with Fig. 4, the values of Shi's samples 1B and 1D appear to be almost identical to the data points of Sample WS-55-3, which has a Ho of 54, Hc of 16 and a Tc of 2.5 hours. One of ordinary skill in the art would find it obvious that Shi's samples 1B and 1D, exhibiting similar values when compared to the aforesaid applicant data would have similar results to the Ho, Hc and Tc values of the applicant's samples. Therefore, interpolation of the applicant's data would yield for Shi's samples 1B and 1D an estimated value of about, Ho: 54-90 (%/h), Hc: 14-22 (%/h) and Tc: 2.5 hours.

10. Claims 3, 5, 6, and 7, are rejected in view of Shi. The references and rejection are incorporated as cited in a previous Office action.

11. **Regarding Claim 8**, Shi discloses, as discussed above, a process of manufacturing a slowly digestible starch product prepared by enzymatically debranching low amylose starches and allow the resultant linear short chains to crystallize to a highly crystalline form, (lines 20-25, col. 2, '571) with an initial hydrolysis rate of less than 300 %/h. (pg 46, Table 1, Applicant) and a Tc of a least 0.5 hours.

12. Regarding claims 14, and 15, Shi discloses the claimed invention, as discussed above including that the Hc is less than 300 %/h for a time greater than one hour.

13. Regarding claims 10, 12, and 13, Shi discloses the claimed invention, as discussed above including the use of slowly digestible starch in a variety of edible

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products such as cereal, bars and dietary supplements. (lines 29-41, col. 5, '571) One of ordinary skill in the art would find it obvious that dietary supplements would include tablets.

14. **Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shi, Y.C., in view of. Haralampu, S. G.**

15. Haralampu ('090)discloses:

g. Increased fecal bulk . . .increased excretion of butyrate and acetate [in the colon] (lines 25-28 col1, '090)

h. Slow hydrolysis of resistant starch . . . controlling glycemic plasma responses, (lines 34-37 col. 1, '090)

i. The granular resistant starch . . . co-processed with hydrocolloids, polymers, gums, modified starches . . . to change the functional properties, (lines 33-38 col. 2, '090 )

j. Batch co-processed with hydrocolloid sodium carboxymethyl cellulose . . . added on a 10 % basis relative to the starch, (lines 14-18, col. 8, '090)

16. **Regarding claim 9**, Shi discloses the claimed invention, as discussed above, but lacks the use of an additive. Haralampu discloses the use of additives to change the functional properties of the resistant starch. (lines 33-38 col. 2, '090)

17. Shi and Haralampu are analogous art in that both are concerned with the modification of starches to form a slowly digestible starch.

18. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the methods of Shi to produce food items useful in controlling

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glycemic plasma responses, (lines 34-37 col. 1, '090), to produce physiological benefits of fiber, such as increased fecal bulk, and increased excretion of butyrate and acetate in the colon. (lines 25-28, col.1, '090).

19. Regarding claim 11, Shi and Haralampu disclose the claimed invention, as discussed above, including that the starch product has a percentage of soluble fibers. (lines 14-18, col. 8, '090)

### ***Response to Amendments***

20. Applicant have amended specification in respect to the proper use of trademarks, the objection to the specification is withdrawn

21. Applicant having cancelled claim 4, and amended claims 9-10 to comply with examiner's 35 USC 112 objections, the objections to said claims are withdrawn.

22. Applicant having amended claim 1, the 102(b) rejections of claims 1-8 and 10 are withdrawn.

### ***Response to Arguments***

23. Applicant states, on page 7, that the claims as amended clearly define over Shi and all other art of record. This is not persuasive because, as stated above, Shi's samples 1B and 1D exhibit Ho, Hc and Tc values that anticipate the applicant's amended claims.

24. Applicant states, on page 7, that Haralampu does not alleviate the deficiencies of Shi. This is not persuasive because, as stated above, Shi anticipates the instant application, and in combination with Haralampu addresses the use of additives to modify the functional properties of the resistant starch.

***Conclusion***

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY W. ANDERSON whose telephone number is (571)270-3734. The examiner can normally be reached on 7 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jwa

/KEITH D. HENDRICKS/  
Supervisory Patent Examiner, Art Unit 1794